

**RECEIVED
CENTRAL FAX CENTER****OCT 09 2006****Attorney Dkt. No. 51275/149****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
VIA FACSIMILE****In re: application of:
Theoharis C. Theoharides
Filing date: 03/20/2004
Serial No.: 10/811,828****Group Art Unit: 1655
Examiner: Patricia Leith****Priority from copending PCT/US02/00476, filed 01/03/2002,
copending USSN 09/771,669, filed 01/30/2001, and USSN 09/056,707, filed
4/8/1998, now USPN 6,689,748, issued 2/10/2004
For: Composition For Protection Against Superficial Vasodilator Flush Syndrome****Petition Under 37 CFR 1.144****Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450
Mail Stop: TC1600 Director Bruce Kisliak****Sir:**

Applicant is petitioning for reversal of the Examiner's restriction requirement initially mailed 05/04/2006, and maintained in her Office Action mailed 08/28/2006..

The claims in question are set forth below. All of the claims are the original claims.

40. A composition for protecting a subject from the inflammatory disease superficial vasodilator flush syndrome, said composition comprising a non-bovine heavily sulfated proteoglycan, olive kernel extract, a flavonoid compound, bitter willow bark extract, and, optionally, cyproheptadine or azatadine.

41. The composition of claim 40, wherein said proteoglycan is sulfated chondroitin sulfate.

42. The composition of claim 40, wherein said flavonoid compound is quercetin, myricetin or genistein.

43. The composition according to claim 1, wherein said inflammatory disease is superficial vasodilation flush syndrome, said composition comprising 50 mg non-

bovine chondroitin sulfate; olive kernel extract, 150-600 mg; 150-350 mg quercetin; 5% by weight bitter willow bark extract; and, optionally, 4 mg cypheptadine or azatadine, administered daily.

44. A method of protecting against superficial vasodilator flush syndrome, comprising the oral administration of the composition of claim 40 or claim 43.

45. The composition of claim 1, wherein said syndrome is selected from the group consisting of carcinoid-induced flush, niacin-induced flush, mesenteric fraction syndrome-induced flush, and serotonin syndrome-induced flush.

As to the flavonoid component of generic claim 1, contrary to the examiner's assertion, all flavonoids have the same basic three-ring structure shown as Fig. 1 in applicant's traversal of 06/21/2006. The flavonoid species quercetin, myricetin and and genestein listed in claim 42 are merely claimed members of the same family. Looking at Fig. 2, also of record, it can be seen that quercetin and myricetin differ from each other only by a small functional group, namely, a hydroxyl group at R2. Looking at Fig. 3, also of record, it can be seen that genestein has the same empirical formula as quercetin. All known members of the family of flavonoids have, contrary to the examiner's assertion, the same pharmacological, and differ only in relative strength. The examiner has shown no evidence to the contrary. Hence, applicant submits that this restriction requirement was made in error, and petitions the Director to reverse it.

The examiner has also ruled that the heavily sulfated proteoglycan component of composition claim 40 is too broad, and has ruled that applicant must limit this component to the chondroitin sulfate recited in claim 41. The applicant traversed by a showing that chondroitin sulfate is merely one of a family of molecules more accurately called "glycosaminoglycans" because one of the two sugars is always an amino sugar, e.g., N-acetylglucosamine. Other members of this family are listed and described in the accompanying e-articles with the URLs of <http://biol.lancs.ac.uk/gig/pages/pgpage.htm> and <http://biol.palsley.ac.uk/courses/stfunmac/glossary/proteoglycan.htm>. All

sulfated proteoglycans are generally known in the art to exhibit similar properties, that include cartilage formation and joint lubrication. In the present invention, sulfated proteoglycans are shown to have anti-inflammatory effects. Thus, a search for "sulfated proteoglycans" will uncover chondroitin sulfate and other glycosaminoglycans suitable for practicing this invention. Applicant submits that it would be appropriate for the Director to withdraw this restriction requirement.

The Director is also respectfully reminded that there is an Office Action pending in this application.

10/9/2006

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Respectfully submitted,



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